

## REMARKS

Applicants wish to thank the Examiner for the time and care taken in acting on the instant application in the paper mailed April 4, 2007. Claims 1-21 are pending herein. New claims 15 through 21 have been added to support for which may be found in the originally filed claims.

Claim 1 has been amended to further clarify the composition.

The Examiner has apparently objected to the disclosure due to certain informalities. The Examiner has also rejected claims 5, 8, 12 and 14 under 35 U.S.C. §112, 2<sup>nd</sup> paragraph as being indefinite. The Examiner has also rejected claims 1-6, 8 and 13-14 under U.S.C. §103(a) as unpatentable over Illum, U.S. Patent No. 5,863,554 in view of Ko et al. (Journal of Microencapsulation, 1998). Claim 7 has been rejected as obvious and unpatentable over Illum in view of Ko and Patel. Claims 9-10 and 12 have been rejected as obvious and unpatentable over Illum, Ko and Dondeti. Claim 11 has been rejected as obvious and unpatentable over Illum, Ko and Glass.

Applicants traverse each and every rejection to the extent that they may be maintained by the Examiner.

Claims 5, 8, 12 and 14 are rejected under 35 U.S.C. §112, 2<sup>nd</sup> paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 11 rejected under 35 U.S.C. §112, 2<sup>nd</sup> paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has amended the rejected claims to otherwise overcome the instant rejections. Favorable reconsideration is requested.

Applicants have traversed the Examiner's rejection of Claims 1-6, 8 and 13-14 under 35 U.S.C. §103(a) as being unpatentable over Illum (US Pat. No. 5,863,554), in view of Ko et al. (Journal of Microencapsulation 1998).

The claimed invention comprises a high level of lipophilic character which retains the "sexual hormone drug" within the nasal passages to maintain high in vivo drug concentrations.

This has been problematic in the past due to the bodies' natural tendencies to enzymatically clear and break down of the drug. By incorporating the drug into a lipophilic carrier, a high bioavailability of the drug results. In turn, the higher serum levels in the plasma, result in a higher serum level profile in the patient.

The Examiner has cited Illum. Illum teaches the use of microspheres containing an active drug. The microspheres are the product resulting from formation of an oil-water emulsion for administration of the therapeutic agent. The microspheres of Illum are formed of protein, polysaccharides, synthetic polymers, gelatine, collagen, starch and dextran, among other constituents.

The Examiner has apparently added the teachings of Ko to show the use of testosterone in nasal applications.

However, neither Illum nor Ko teach the use of such high concentrations of lipophilic agents. For example, Illum teaches the use of as much as 10% phospholipids ( col. 4, lines 18-26) to enhance membrane permeability (col. 6, lines 19-37).

In turn, Ko teaches the creation of an oil phase with rough 45% (parts-by-weight) of soybean oil (pg. 199).

In sharp contrast, the claimed invention teaches a higher lipophilic concentration for a different reason. The claimed invention carries at least 60% lipophilic carrier which is intended to stabilize the suspension and maintain consistent serum levels upon administration.

The cited art simply does not suggest, teach or otherwise disclose the claimed invention.

Applicant has traversed the Examiner's rejection of Claim 7 under 35 U.S.C. §103(a) as being unpatentable over Illum (US Pat. No. 5,863,554), in view of Ko et al. (Journal of Microencapsulation 1998) as applied to claims 1-6, 8, 13 and 14 above, and further in view of Patel et al. (U.S. Patent No. 6,248,363).

Claim 7 is dependent, in series, on earlier rejected claim 1. The Examiner further cited Patel as teaching that drug bio-availability can be improved by microglycerides and surfactants. However, the Examiner has failed to show how Patel remedies the deficiencies of Illum and Ko, (earlier cited). Patel does not teach a high lipophilic concentration.

Accordingly, the present rejection also fails. Favorable reconsideration of the rejected claims is respectfully requested.

Applicant has traversed the Examiner's rejection of Claims 9-10, and 12 under 35 U.S.C. §103(a) as being unpatentable over Illum (US Pat. No. 5,863,554), in view of Ko et al. (Journal of Microencapsulation 1998) as applied to claims 1-6, 8, 13 and 14 above, and further in view of Dondeti (International Journal of Pharmaceutics, 1996).

The Examiner has further cited Dondeti as teaching formulation parameters that affect nasal absorption of drugs. The rejected claims are dependent on earlier rejected claim 1. Apart from problems with Dondeti teaching solid compositions and not liquids, Dondeti does nothing to remedy the deficiencies of Illum and Ko, (earlier cited). Since the Examiner has done nothing to show how Dondeti cures the deficiencies of Illum and Ko in the earlier rejection, the present rejection also fails.

Applicants respectfully request favorable reconsideration of the rejected claims.

Applicants have traversed the Examiner's rejection of claim 11 under 35 U.S.C. §103(a) as being unpatentable over Illum (US Pat. No. 5,863,554), in view of Ko et al. (Journal of Microencapsulation 1998) and further in view of Glass, (US Pat. No. 5,897,894). The Examiner has further cited Glass as teaching liquid oils which can be thickened to increase viscosity. Claim 11 is dependent upon earlier rejected claim 1, in series. The Examiner has failed to show how Glass remedies the deficiencies of Illum and Ko, (also earlier cited), and thus fails to show how the cited references meet the claimed invention. Again, the high lipophilic concentration is absent.

Favorable reconsideration is respectfully requested.

#### CONCLUSION

Favorable reconsideration of all claims pending herein is respectfully requested. The Examiner is invited to contact Applicant's representative (below) if questions arise.

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Respectfully submitted,

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